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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,673	07/20/2000	BRUCE PAUL DAGGY	C75087	9337

7590 01/24/2006

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/600,673	Applicant(s) DAGGY ET AL.	
	Examiner Anne L. Holleran	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/2005 has been entered.

1. The amendment filed 10/24/2005 is acknowledged.

Claims 19-34 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

3. The rejection of claims 19-34 under 35 U.S.C. 102(e) as being anticipated by Dressman (Dressman et al, U.S. Patent 5,789,393 issued 08/04/1998; effective filing date 02/21/1992) is withdrawn because Dressman does not appear to teach the administration of methylcellulose having a viscosity of 4000 centipose. Applicant is advised that should this limitation be removed, this rejection will be reinstated.

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4. The rejection of claims 19-23, 25-31, 33 and 34 under 35 U.S.C. 103(a) as being obvious over Dressman (Dressman et al, U.S. Patent 5,789,393 issued 08/04/1998; effective filing date 02/21/1992) in view of Durlach (U.S. Patent 4,232,054, issued 11/4/1980) is withdrawn because Dressman does not appear to teach the administration of methylcellulose having a viscosity of 4000 centipoise. Applicant is advised that should this limitation be removed, this rejection will be reinstated.

New Grounds of Rejection:

5. Claim 19 is objected to because “centipoises” is misspelled as “centipose”.

6. Claims 19-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 27 are indefinite because they contain the recitation of “methylcellulose having a viscosity of 4000 centipoise” without setting forth the conditions under which viscosity is measured. Viscosity varies with temperature and inclusion of conditions under which the measurement is taken are needed for the information to be useful.

7. Claims 19-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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This is a new matter rejection. The basis for this rejection is that the specification fails to support claims for methods of treatment consisting essentially of administering methylcellulose having a viscosity of 4000 centipoise. The administration of methylcellulose of specific viscosities does not appear to have been originally contemplated at the time of filing.

Applicant points to support, at page 7 of the specification and in documents incorporated by reference, for the limitation of methylcellulose having a viscosity of 4000 centipoise. However, a review of the passage on page 7 fails to provide either explicit or implicit support for this limitation. Furthermore, the reference in the specification to documents incorporated by reference is made in the context of descriptive support for alternative formulations of methylcellulose, and not with respect to the viscosity of the administered methylcellulose. Therefore, applicant does not appear to have been in possession of the claimed inventions at the time of filing because the specific limitation of viscosity of the administered methylcellulose does not appear to have been contemplated at the time of filing.

8. Claims 19-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection is that one of skill in the art cannot use the specification to make or use the claimed inventions without undue experimentation.

The claimed inventions are drawn to methods for reduction of the incidence of colorectal cancer or the reduction of the incidence of breast cancer. Therefore, these inventions read on methods for the prevention of colorectal or breast cancer.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The guidance presented in the specification is insufficient with respect to the claimed methods. The claimed methods are drawn to methods for treating humans comprising the prevention of cancer by the administration of methylcellulose alone or in combination with wheat bran, whereas the specification provides data from a rat model for the effect of psyllium fiber in combination with wheat bran. The specification lacks any reasoning for why data from an experiment where the fiber administered is psyllium may be extrapolated to methods for preventing cancer in humans where the fiber administered is methylcellulose alone or in combination with wheat bran.

Additionally, the art indicates that in the case of colorectal cancer, there appears to be a lack of consensus in the field of colorectal cancer prevention and dietary fiber. Baron (Baron, J.A., JAMA, 294(22): 2904-2906, 2005) teaches that epidemiological studies have found the intake of dietary fiber to be either protective, to have no effect or even to cause an increase risk in colorectal cancer (see page 2904, 2nd column). Furthermore, it appears that animal models do

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not correlate with human epidemiological studies (page 2905, 1st column, 3rd full paragraph).

Also, there appears to be a relationship between type of fiber and colorectal cancer risk (page 2905, 1st column, 3rd full paragraph). Therefore, the working example in the specification, which is directed to the use of psyllium fiber, does not appear to be predictive for the use of methylcellulose fiber, as stipulated in the claims, in the prevention of colorectal cancer.

The specification also does not appear to provide guidance with respect to effect of methylcellulose and prevention of breast cancer, because the working example is directed to the use of psyllium and the prevention of colorectal cancer in rats. In the art, there appears to be a lack of consensus for the effect of fiber in general and no information with regard to the specific fiber, methylcellulose and the prevention of breast cancer. One study reports no effect of dietary fiber and the prevention of breast cancer (see Cho, W. et al. Cancer Epidemiology, Biomarkers & Prevention, 12: 1153-1158, 2003; page 1153, abstract and also 2nd column, 2nd paragraph). Another study does support an effect of dietary fiber in general (see Mattisson, I., et al., British Journal of Cancer, 90: 122-127, 2004; page 122, abstract), however, the results are for dietary fiber in general and not specifically to methylcellulose. Dietary fiber is often ingested in the form of whole grains and the protective effect of ingesting fiber may be related to other nutrients found in whole grains and not merely to presence of fiber. Slavin (Slavin, J., Proc. Nutr. Soc., 62(1): 129-134, 2003; abstract only) teaches that whole grains are sources of fiber, and additionally antioxidants, trace minerals, phenolic compounds, phytate, and phyto-estrogens, which are also nutrients associated with disease prevention.

In view of the fact that the claims are drawn to methods for cancer prevention in humans (colorectal or breast cancer), and in view of the fact that the working example demonstrates the

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use of a fiber (psyllium) that is not methylcellulose in an animal model, and in view of the state of the art indicating that the role of fiber in general has not been established in the prevention of either colorectal cancer or breast cancer, in view of the fact that there appears to be no data on the role of methylcellulose, specifically, in the prevention of either colorectal cancer or breast cancer, the practice of the claimed inventions would require further and undue experimentation of the part of one of skill in the art. The further experimentation would be undue experimentation because it appears that there is no expectation of success based on the current state of the art or on the data provided in the specification in achieving the goal of prevention of cancer in humans by the administration of methylcellulose fiber.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Tuesdays, Wednesdays and Fridays, 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
January 12, 2006



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER